DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 16, 2015

Respironics, Inc.
Daniela Aizpitarte
Regulatory Affairs Engineer
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K142988
Trade/Device Name: Sleepware G3
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLZ, MNR, OLV
Dated: February 9, 2015
Received: February 10, 2015

Dear Ms. Aizpitarte,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142988

Device Name
Sleepware G3

Indications for Use *(Describe)*
Sleepware G3 is a software application used for analysis (automatic and manual scoring), display, retrieval, summarization, report generation and networking of data received from monitoring devices used to categorize sleep related events that help aid in the diagnosis of sleep related disorders. It is indicated for use with infant or adult patients in a clinical environment by or on the order of a physician.
The optional Somnolyzer Inside scoring package has the same intended use as Sleepware G3, but is indicated for use with adult patients only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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TAB 5

510(K) SUMMARY

I. Submitter

Official Contact

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Date of Preparation February 9, 2015

II. Device

Name of Device: Sleepware G3

Common/Usual Name: Electroencephalograph analysis software

Classification Name: Automatic Event Detection Software For Polysomnograph With Electroencephalograph (21 CFR 882.1400)

Regulatory Class: II

Primary Product Code: OLZ
Secondary Product Code: MNR, OLV

III. Predicate Devices

- Alice Sleepware Software (K040595)
- Somnolyzer 24x7 (K131994)

These predicates have not been subject to any design-related recalls.

No reference devices were used in this submission.

IV. Device Description

The Sleepware G3 software is a diagnostic tool, used by trained clinical professionals, for managing Respironics polysomnography recorders using a personal computer. The Sleepware G3 software uses data that is stored in the recorder device memory, and then processes this data to display a graphical and statistical analysis for use by the trained clinical professional. It also allows the trained clinical professional to evaluate (score) the recorded respiratory, sleep staging and/or oximetry waveforms to ensure that the patient being monitored is properly diagnosed. The clinician can create unique patient reports for the patient being evaluated, and configure device parameters in the software. Sleepware G3 was formally known as the Alice Sleepware Software cleared in K040595.

Somnolyzer 24x7 is a similar standalone, polysomnography scoring application that provides automated analysis of respiratory, sleep staging and/or oximetry waveforms recorded during sleep studies. Like Sleepware G3, it processes information recorded during sleep with electrodes and sensors attached to the body according to worldwide accepted scoring standards. It then generates results that include quantitative sleep, breathing, and motion parameters, used to evaluate sleep and respiratory-related disorders. Somnolyzer is located on a remote server and is considered to be a software service, unlike Sleepware G3 which is located on a personal computer.

Sleepware G3 is being updated to add the scoring algorithms from the Somnolyzer 24x7 software service as an optional software package. The scoring algorithms from the cleared Somnolyzer 24x7 software were modified to operate in real time, as a sleep study is occurring, and be displayed on the Sleepware G3 user interface.

V. Indications for Use

Sleepware G3 is a software application used for analysis (automatic and manual scoring), display, retrieval, summarization, report generation and networking of data received from monitoring devices used to categorize sleep related events that help aid in the diagnosis of sleep related disorders. It is indicated for use with infant or adult patients in a clinical environment by or on the order of a physician.

The optional Somnolyzer Inside scoring package has the same intended use as Sleepware G3, but is indicated for use with adult patients only.

The indications for use for Sleepware G3 are a combination of the indications for uses of the two predicate devices. Alice Sleepware Software has been updated to include the Somnolyzer 24x7 product cleared in K131994. The patient populations of Somnolyzer 24x7 and Sleepware G3 remain unchanged

in this submission. The Alice Sleepware Software (K040595) was cleared for infant or adult patients, and Somnolyzer 24x7 (K131994) was cleared for adult patients. The optional Somnolyzer 24x7 scoring algorithms being added to Sleepware G3 can only be used on adult patients.

The intended use and purpose of this device has not changed. The Sleepware G3 software with the added Somnolyzer scoring algorithms still allow clinicians to diagnose sleep disorders, and no new diagnostic functions were added. The same scoring rules are used to identify respiratory events, and no new respiratory events have been added. The addition of the algorithms from Somnolyzer 24x7 does not modify the intended use of the Sleepware G3 software package.

VI. Comparison of Technological Characteristics with the Predicate Device

Both the Alice Sleepware and Somnolyzer 24x7 predicate devices and the Sleepware G3 subject device are software products designed to detect events for polysomnography with electroencephalography. The subject and predicate devices are based on the following same technological elements:

- Same intended use as the Somnolyzer 24x7 software (K131994) and Alice Sleepware Software (K040595). The indications for use that were previously cleared for each software program have also been retained.
- Same control mechanism and real-time operating principle as the Alice Sleepware Software (K040595).
- Same technology as the Somnolyzer 24x7 software (K131994) and Alice Sleepware Software (K040595).

The following differences exist between the subject and predicate devices:

- **Modification #1:** Added Somnolyzer 24x7 scoring algorithms to Sleepware G3 as an optional software package

The Somnolyzer 24x7 scoring algorithms were modified to display results in real time, as the sleep study is progressing. The algorithms were designed to fulfill the same scoring rules as the predicate Somnolyzer 24x7 version 2.5 (K131994). This modification required a change in coding language.

- **Modification #2:** Confidence Trend

Respiratory event detection confidence trends were added to the Somnolyzer plug-in. The information used to derive the trend data is based off the signal quality of the channels throughout the acquisition and the scored events.

The product labeling was updated to instruct the sleep scoring technicians to review sections of data marked as yellow and red. This feature allows for the sleep labs to increase scoring efficiency by reducing the amount of time it takes to score a sleep study.

- **Modification #3:** User Interface changes to accommodate for Somnolyzer additions

The Sleepware G3 user interface has been modified from the predicate devices to display Somnolyzer scoring in real time. The Somnolyzer scoring package has been integrated into the configuration and settings of the Sleepware G3 program to allow the user to access and launch the scoring package.

VII. Performance Data:

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered to have a "moderate" level of concern, since a failure or latent flaw in the software could result in minor harm to the patient.

Non-Clinical Tests

Respironics has determined that the modifications discussed in this submission have no impact on the safety and effectiveness of the Sleepware G3 with Somnolyzer Inside software. Software verification and validation included software code reviews, automated testing, bench verification testing and labeling review.

Testing confirmed that the Somnolyzer auto-scoring algorithms perform equivalently to the device predicate algorithms in the Somnolyzer 24x7 software (K131994). Overall testing of Sleepware G3 with Somnolyzer Inside package showed that the plug-in has been successfully integrated and all product requirements have been met. The verification and validation testing demonstrated that safety and effectiveness has not been inadvertently affected by modifications to the system.

Testing confirmed that the Sleepware G3 performs equivalently to the device predicate Alice Sleepware Software (K040595). All tests had passing results.

Clinical Tests

Clinical tests were not required to demonstrate the safety and effectiveness of Sleepware G3. Product functionality has been adequately assessed by non-clinical tests.

VIII. Conclusion

Sleepware G3 has passed all of the aforementioned non-clinical tests and required no clinical tests in order to demonstrate safety or effectiveness. It is therefore concluded that Sleepware G3 is substantially equivalent to the predicate device.

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